

Laser Thermokeratoplasty

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What is the best way for refractive surgeons to treat hyperopia? This is the "burning question" in today's refractive community. Recently, the U.S. FDA approved the VISX excimer laser for the treatment of hyperopia. However, continued progress is also being made in using laser thermokeratoplasty in the treatment of hyperopia. With this in mind, Douglas D. Koch, MD spoke on "Laser Thermokeratoplasty" at the 1998 AAO annual meeting in New Orleans, LA.

Historically, Summit Technologies, Inc. conducted FDA-monitored trials in the US, which have since been discontinued. According to Dr. Koch, large initial corrections were achieved, but there were problems with ongoing regression, even as late as 3 years postoperatively. In addition, within 1 year follow-up, over 10% of patients lost 2 or more lines of BCVA due to irregular astigmatism. The Technomed device is continuing to undergo clinical trials, but Dr. Koch stated, "I am unaware of any published data."

Dr. Koch presented data using the Non-contact Holmium laser, known as the "YAG LTK-Sun 1000 Corneal Shaping System" by Sunrise Technologies, Inc. Dr. Koch acknowledged that he is both a paid consultant to this company and has a financial interest in this equipment.

In the FDA Phase IIa studies, 20 eyes were treated with one ring of YAG LTK treatment at 6 mm. Eight eyes were treated with 2 rings in a staggered, or offset pattern: one ring at 6 mm, and a second ring at 7 mm, rotated 22.5 degrees with respect to the first ring.

At 24 months follow-up mean refractive correction was -0.5 D in the 1-ring group, and -1.5 D in the 2-ring group, with essentially no change between 12 and 24 months. Regression occurred in both groups. Mean regression between 6 and 24 months was 0.1 D in the 1-ring group, and 0.4 D in the 2-ring group. Again, there was essentially no change between 12 and 24 months.

Importantly, Dr. Koch stated, "there was no loss of 2 or more lines of best corrected visual acuity (BCVA) or contrast sensitivity in any of the patients. Computerized videokeratography (CVK) was used to document peripheral corneal flattening in the treated regions, with induced corneal steepening centrally. According to CVK, this pattern is enhanced by using the 2-ring treatment parameter compared to 1-ring.

The pattern of treatment was altered in the Phase III study based on studies by Vinciguerra and colleagues, which showed that greater corrections and larger effective corrected zones could be achieved by aligning the spots in a radial, rather than an offset pattern. Accordingly, treatment in the Phase III study involved 2 rings placed at 6 and 7 mm, and aligned radially.

Of 288 eyes with at least 3 months of follow-up, the percentage of patients seeing 20/25 or better uncorrected was 54% at 3 months and 56% at 6 months. The percentage of eyes within ± 0.5 D of emmetropia was 61% at 3 months and 62% at 6 months. No patients lost 2 or more lines of visual acuity by the 6 month interval. There were no sight-threatening complications in this study group.

According to Dr. Koch, "clinical studies of astigmatism correction by LTK have shown less stability than hyperopic treatments." Thus far, no clinically acceptable treatment patterns have been developed for the correction of astigmatism using

LTK. Anecdotally, Dr. Koch said that "several investigators have reported excellent results using LTK to treat over-corrections following LASIK."

In summary, Laser Thermokeratoplasty using the YAG SLK-Sun 1000 Corneal Shaping System was found to be safe and effective for the treatment of simple hyperopia. Further studies will be necessary to replicate these results, and to devise more effective treatment parameters for astigmatism using this modality.